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4

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I also certify that the attached copy of the request for grant of a Patent (Form 1/77) bears an amendment, effected by this office, following a request by the applicant and agreed to by the Comptroller-General.

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Signed R. Mahoney

Dated 22 September 1999

Patents Form 1/77

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04AUG98 E380385-1 C43066
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Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office

Cardiff Road
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1. Your reference AM/GFIX

2. Patent a *(The Pate* **9816802.4** 3 AUG 1998

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

ANTHONY WALTER ANSON.
101, MARTINDALE ROAD
HOUNSLOW
MIDDLSX TW4 7EZ

Patents ADP number *(if you know it)* 38102310001

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention "A GRAFT FIXATOR SYSTEM"

1a/1ac

5. Name of your agent *(if you have one)* N/A

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

ANSON MEDICAL LTD.
THE INNOVATION CENTRE
68, MILTON PARK
ABINGDON 6647164001
OXFORD OX14 4RX.

Williams Powell & Associates
4 St Paul's Churchyard
London
EC4M 8AY

Patents ADP number *(if you know it)* 58303160001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*
N/A		

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*
N/A	

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

N/A

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	
Description	6
Claim(s)	
Abstract	
Drawing(s)	10 ONLY

10. If you are also filing any of the following, state how many against each item.

Priority documents	1
Translations of priority documents	—
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	—
Request for preliminary examination and search *(Patents Form 9/77)*	—
Request for substantive examination *(Patents Form 10/77)*	—
Any other documents *(please specify)*	—

11. I/We request the grant of a patent on the basis of this application.

Signature [signature] Date 3/8/98

12. Name and daytime telephone number of person to contact in the United Kingdom A.W. ANSON 01235 862122

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After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

a) If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500505.

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A Graft Fixator System

This disclosure concerns a method for attaching, retaining and sealing polymeric or elastomeric graft materials to natural tissue within a living organism. In particular a method of attaching tubular grafts made from woven, moulded or extruded materials within a natural conduit such as an artery, by means of a fixation or series of fixation devices.

For clinical applications, flexible conduits made of synthetic polymers known as tubular grafts, are commonly used to replace natural tissue which is diseased or has suffered trauma. Commonly and known in the art, grafts are sutured in place or held in place by stents with or without barb arrangements attached to the graft.. Other types of flat graft or patches are used to cover a tissue damage, these are also sutured or stapled in position. The fixator here described is arranged so that fully invasive surgery is not required, access to a site within a living organism is facilitated by minimally invasive or key-hole surgery which include endovascular, percutaneous or transluminal approach.

Surgery associated with the vascular system is one of the main application for tubular graft usage, other fluid carrying conduits also employ tubular grafts to maintain luminal patency. Graft fixation using minimally invasive or key-hole surgery techniques can also benefit from the graft fixation system herein described.

Instead of integrating a retaining device such as a stent directly with the graft for retention and dilation, an independent system that can be used with various forms of graft, is here proposed.

The retaining systems used to fix and secure grafts consists of two components: An introducer and the fixation devices.

The introducer is a catheter constructed of suitable flexible material, substantially round in section and of a diameter that can pass through natural body conduits or small incisions, to reach a site that may require a tubular graft or flat, patching material to effect a surgical repair to body parts.

The fixation device is constructed of a material that has sufficient elastic or shape memory recovery properties to deformed into a substantially straight form and may be constrained in said form within a catheter.

A preferred embodiment of the fixator consists of a plurality of wires laying parallel to each other and connected together in the centre of their long axis preferably by welding or other mechanical fixation means such as binding with a wire or sheathing with a bush of metal or a polymer.

Two, three, four or more wires may be connected at their central portion; the geometry at the leading and trailing ends of the wire would be similar to a marine anchor, preferably having equi-distance between anchoring points. A fixator can be constructed of round, square or triangular section wire, all these types of construction would be connected in their central area, as described . A four wire version construction , in plan would be cruciform, the three wire would be tri-form, two wires lay together in parallel the shape of one fixator wire being a mirror image of the first.

Each wire, preferably constructed of an equi-atomic nickel-titanium shape memory alloy has, by elastic recovery or by thermally induced shape recovery means, a geometry which forms into a shape which when introduced through puncturable materials, retains one puncturable material in relation to other puncturable material. To puncture said materials, each wire has a leading edge sharpened, the trailing edges being flat.

Fixator wires are arranged so that a point sharpening process produces a single needle-like point of elongate ellipsoidal form or a trocar when the wires are in intimate contact as said deformed, straight wires.

In one embodiment, a plurality of fixation devices are constrained in a delivery catheter and ejected by a flexible pusher wire that pushes said fixators out. The quantity of fixators ejected being appropriate to the physiological site and conduit geometry, strength and size. Another embodiment has individual fixators that may be deployed one at a time by loading the delivery catheter with a single unit, ejecting said fixator and re-loading the catheter.

Alternatively, an open ring of wire constructed of a material exhibiting thermal effect shape recovery or by elastic recovery, can be the method for graft fixation. The ring may be of circular form or elliptical. The dimensions of the fully deployed ring fixator are arranged so that suitable forces are generated to ensure intimate contact between graft and natural tissue.

The ring is deformed into a straight form by urging it into the bore of a substantially straight catheter. It is then transported within the lumen of the catheter and extruded from its proximal end . The means for ejecting the ring fixator is a pushing wire capable of exerting sufficient axial force on the fixator, causing it to travel through the lumen of said catheter and penetrating puncturable materials. Subsequent to penetration of puncturable material the ring regains its round or elliptical shape, effecting fixation of puncturable materials.

Other forms of fixation devices such as a helix of wire formed into an open annulus whose leading edge, which is suitably sharpened to a point, may be arranged to be rotatable so that the leading edge continually passes through a circular graft and conduit as a screw thread, subtending an annular track around the circumference of graft and

conduit. If the diameter of the central axis of the annulus corresponds to the nominal diameter of the graft\conduit, an efficient fixation of graft and conduit may be expected.

A specific application of the preferred fixator system is for the fixation of a graft in the human aorta for the repair of abdominal aortic aneurysms. The graft, typically a woven or knitted polyester, tubular bifurcated graft or a simple straight or tapered tube, is attached around the fixator catheter and compacted to reduce its cross section. This assembly is then placed in a sheathing catheter and introduced using endovascular techniques, to the aneurysmal site. The graft is released from its sheath, being attached to the fixator catheter by a simple fracturable or shearable connector such as a thin suture material. The connector may be disconnected by active mechanical means such as an integrated cutting edge or scissors. Electrical resistance heating of small wire engaged with the catheter-to-graft attachment can be utilised to disconnect the attachment.

The leading end of the fixator catheter is then guided to the inner wall of the graft and a fixing device is ejected. As the fixator is ejected it is urged through the graft and aorta, its shape changing from a nominally straight to multiple-arctuate; each arm facilitating graft fixation.

When the fixators are fully deployed the geometry of each one is arranged so that a small compression force is developed, urging the outer surface of graft in intimate contact with the inner surface of aorta. If intimate contact between the aorta and graft is maintained around the circumference it will ensure that blood does not leak past the graft-aorta connection. The forces that urge the aorta and graft together, caused by the fixators also ensure that the graft cannot migrate and any physiological forces that attempt to radially expand the aorta, will be constrained by said fixator arrangement.

To achieve a leak-free graft connection, several fixators will be required, introduced from inside the lumen of a body conduit. For vascular graft applications an endovascular or transluminal approach will be made, the leading edge of the catheter making a

perpendicular (to the long axis of conduit), approach to the vessel wall. To ensure the perpendicularity of said catheter, a centralising mechanism is first deployed, this establishes the spatial relationship of the catheter, relative to the vessel.

Two sets of elastically deformable strips or wire section material are positioned ninety degrees to each other in plan. The strips or wires can be pulled inside the catheter by means of a pushing or pulling wire. Equally, the retracted strips may be expelled from the constraining catheter by the pulling or pushing wire, they then form two incomplete circles which, during deployment, urge the catheter to the centre of the conduit within which they are positioned, due to the expanding geometry of the releasing strips or wires, the nominal diameter of which is slightly larger than the aorta. The interference between aorta and centralising mechanism is accommodated by the deformability of the wires or strips with which it is in contact..

The retracted centralising mechanism enables the catheter to be transported within a narrow passage without causing interference or trauma to the passage.

Also contained within the catheter is a tube made from an elastically deformable material, preferably super-elastic shape memory alloy. The dimensions of this tube are such that it will allow straightened fixators to pass through its bore without interference. Said tube is configured such that it is extendible or retractable within the catheter, extension and retraction is manually controlled.

The proximal end of said elastic tube is heat-treated to produce a quarter radius that subtends approximately 90° relative to the conduit axis .

The extendible tube may be used to contain the fixators and guide them to their ejection point. An ejection wire, exposed at the distal end of the catheter assembly is employed to eject the fixators; said wire being a sliding fit within the bore of the extendible tube.

Features of the present invention here disclosed will be described, by way of example with reference to the accompanying drawings.

Fig. 1. Is a view of a wire-form fixator [2], connected by welding in the central area. The end termination's of said fixator being sharpened and in unconstrained geometry.

Fig. 2. Illustrates methods of connecting fixator wire-forms [3], preferably by welding [6] but alternatively binding [5], a crimping bush [4]. The cross-section is shown using four wires [7], three wires [8] and two wires [9]

Fig. 3. Shows schematically in cross-section, fixators [12] engaging a graft [10] with aorta [11]

Fig. 4. Shows alternative ring fixator [13] and ring in deformed shape [14]

Fig. 5. Is a view showing ejection of fixators [18] from catheter [17] and deformed and constrained fixators [16] . The ejecting wire [15] exits from the distal end of the catheter.

Fig. 6. Shows an alternative ring fixator [19] being ejected from the tip of the catheter [22]. Means for ejecting ring fixator is by pusher wire [23]. A fully formed ring fixator is shown [13].

Fig 7. Shows embodiments of fixator arrangements in the form of two wire-form [26], three wire-forms [25] and four wire-forms [24].

Fig 8. Shows the embodiment whereby fixators approach a natural tissue [33] conduit at 90° to the long axis. An elastically deformable tube [32] forms a 90° arc when extended from its constraining catheter [34], by means of a pushing or pulling wire [35].

Fig. 9. Shows a means to retract the fixator delivery tube by pulling the pushing\pulling wire [36], causing the tube to be drawn inside the catheter.

Fig10. Shows the centralising wires or strip mechanism [29] in its deployed form and in its retracted form [31]. Also shown are the centralising actuation wire [35] and fixator tube actuation wire [27].. The catheter body [34] is also shown. The centralising mechanism in plan view is illustrated with the extended fixator tube [32].

Fig 1

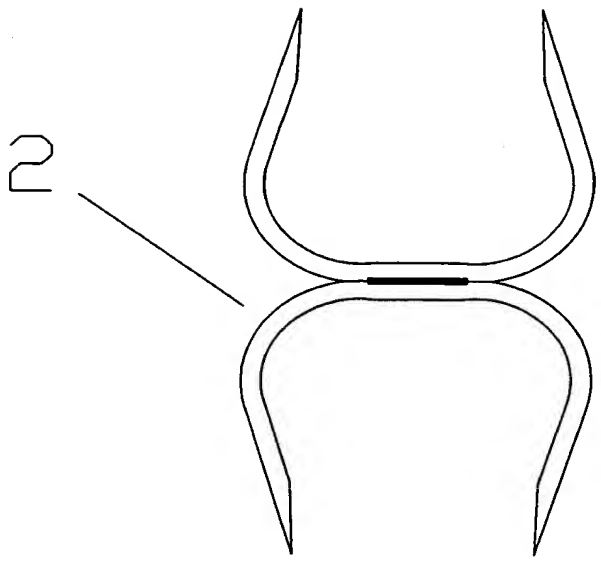


Fig 2

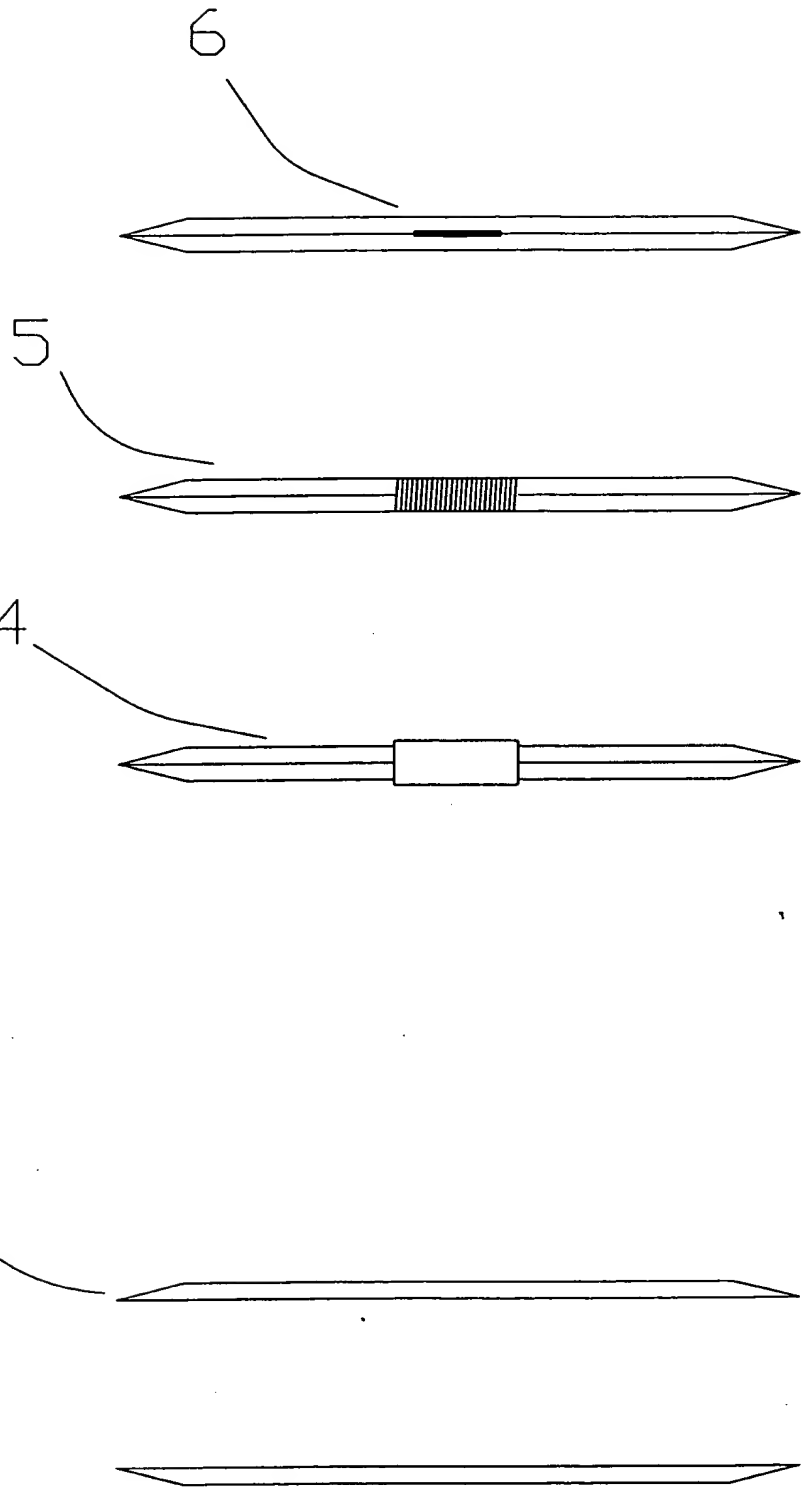


Fig 3

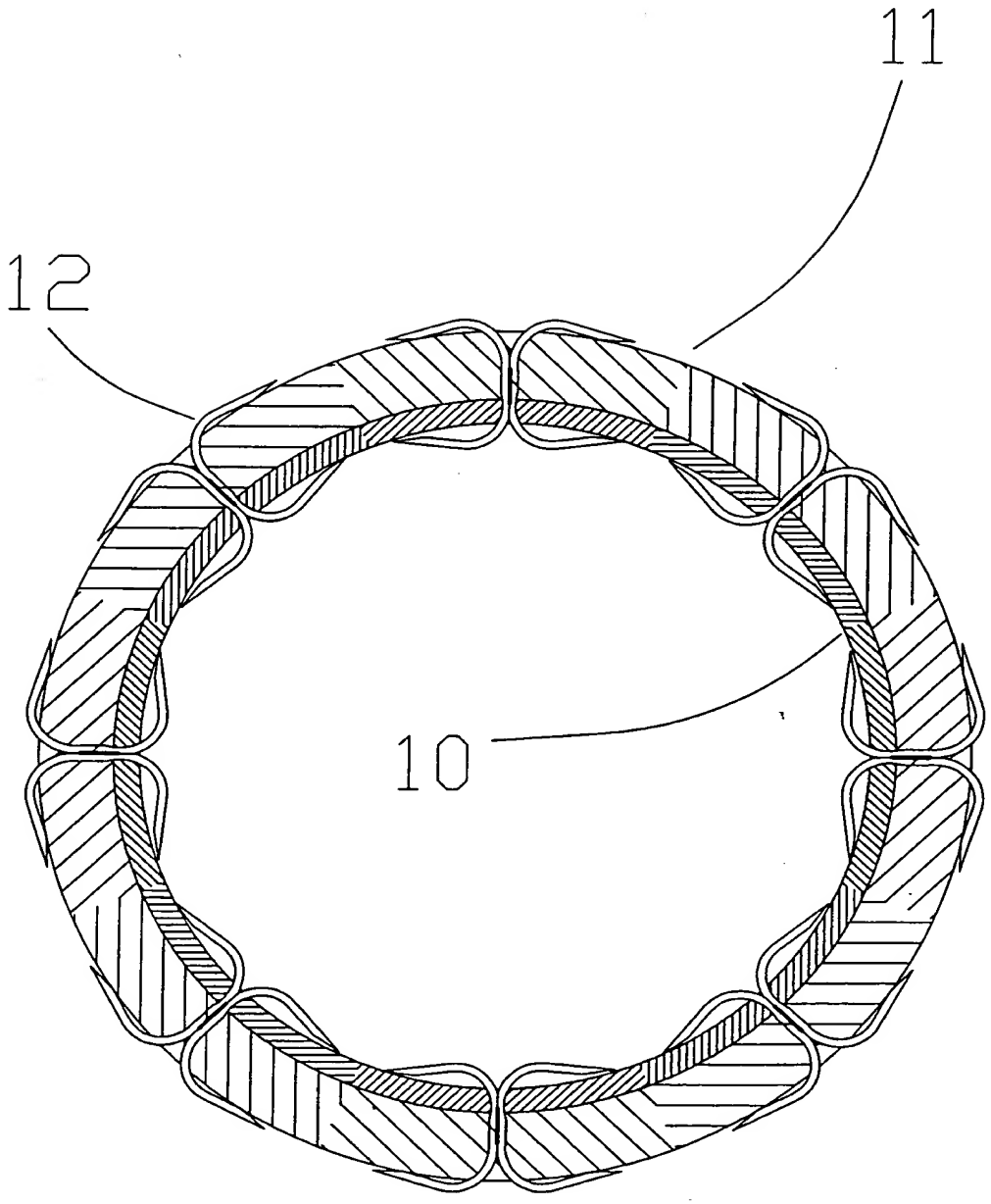


Fig 4

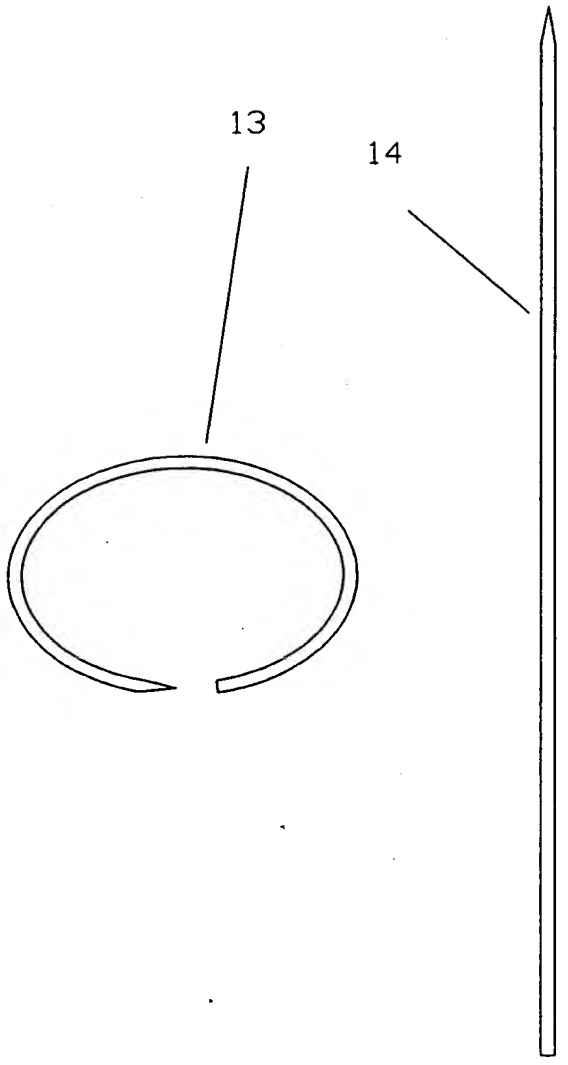


Fig 5

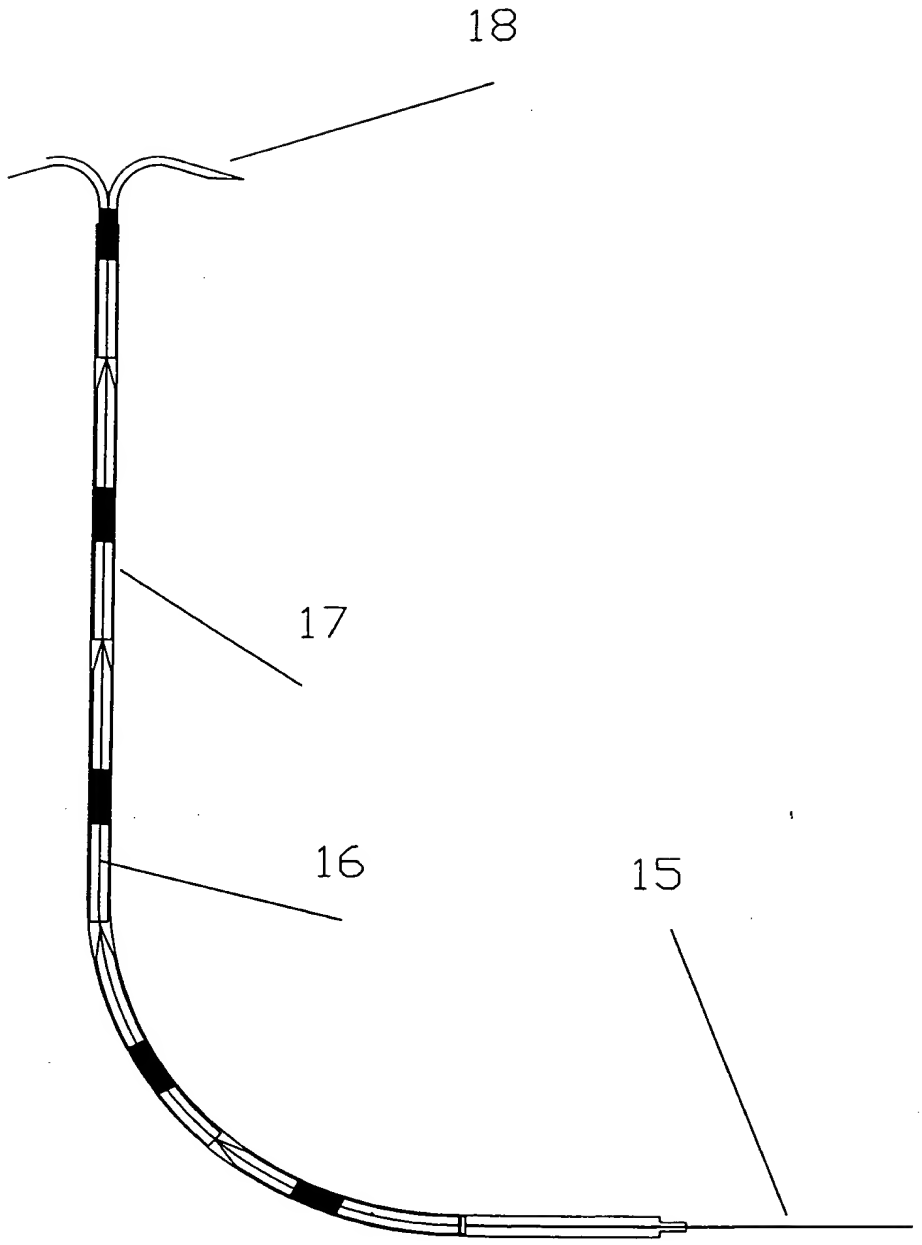


Fig 6

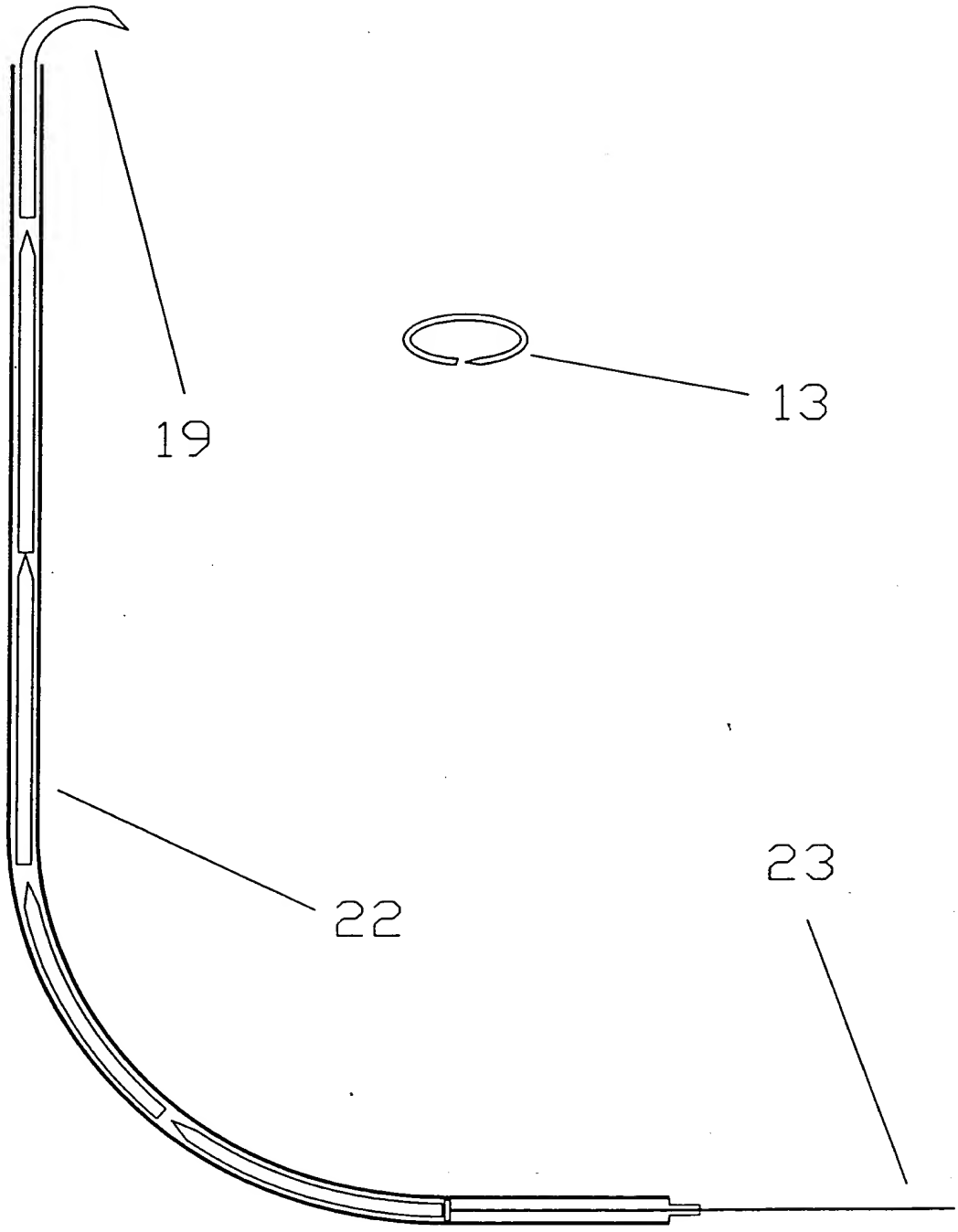


Fig 7

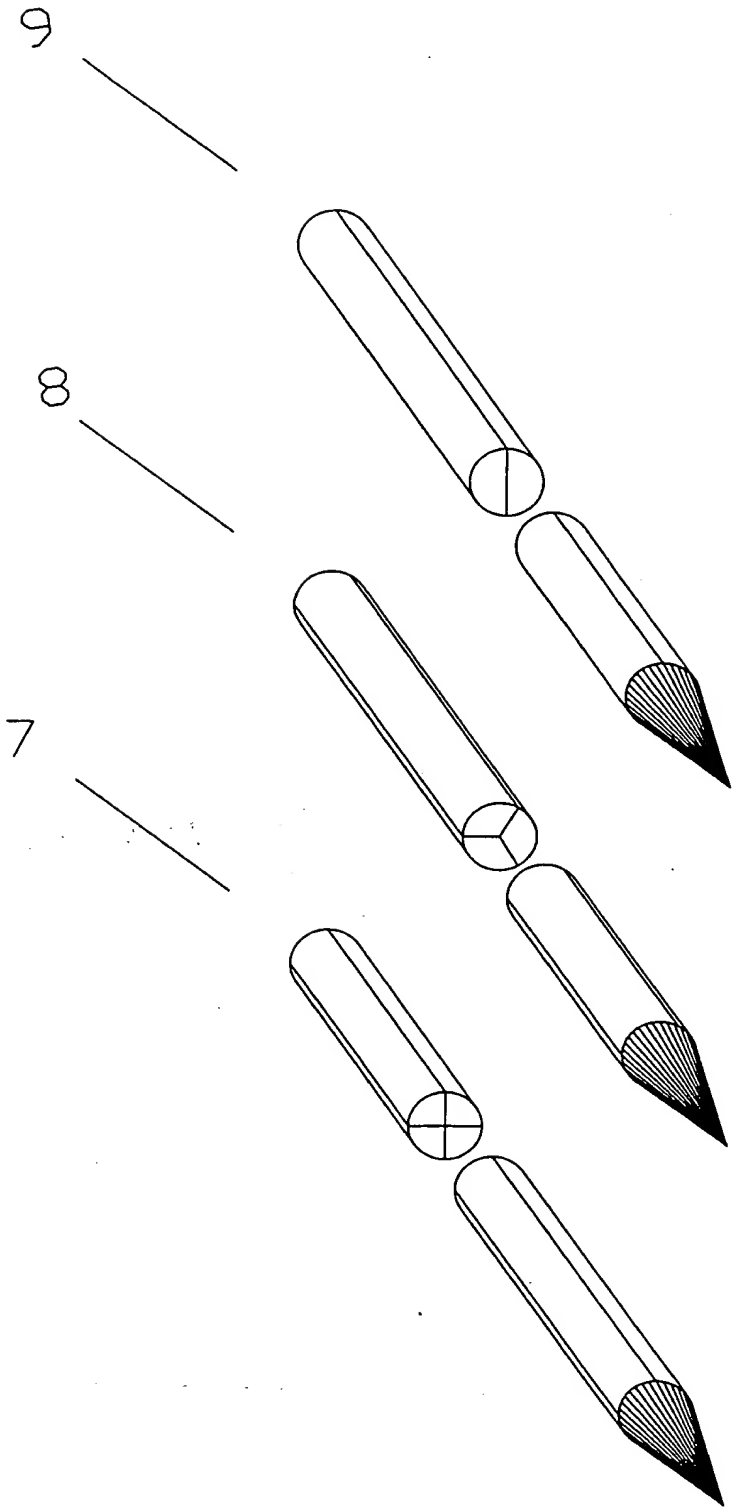


Fig 8

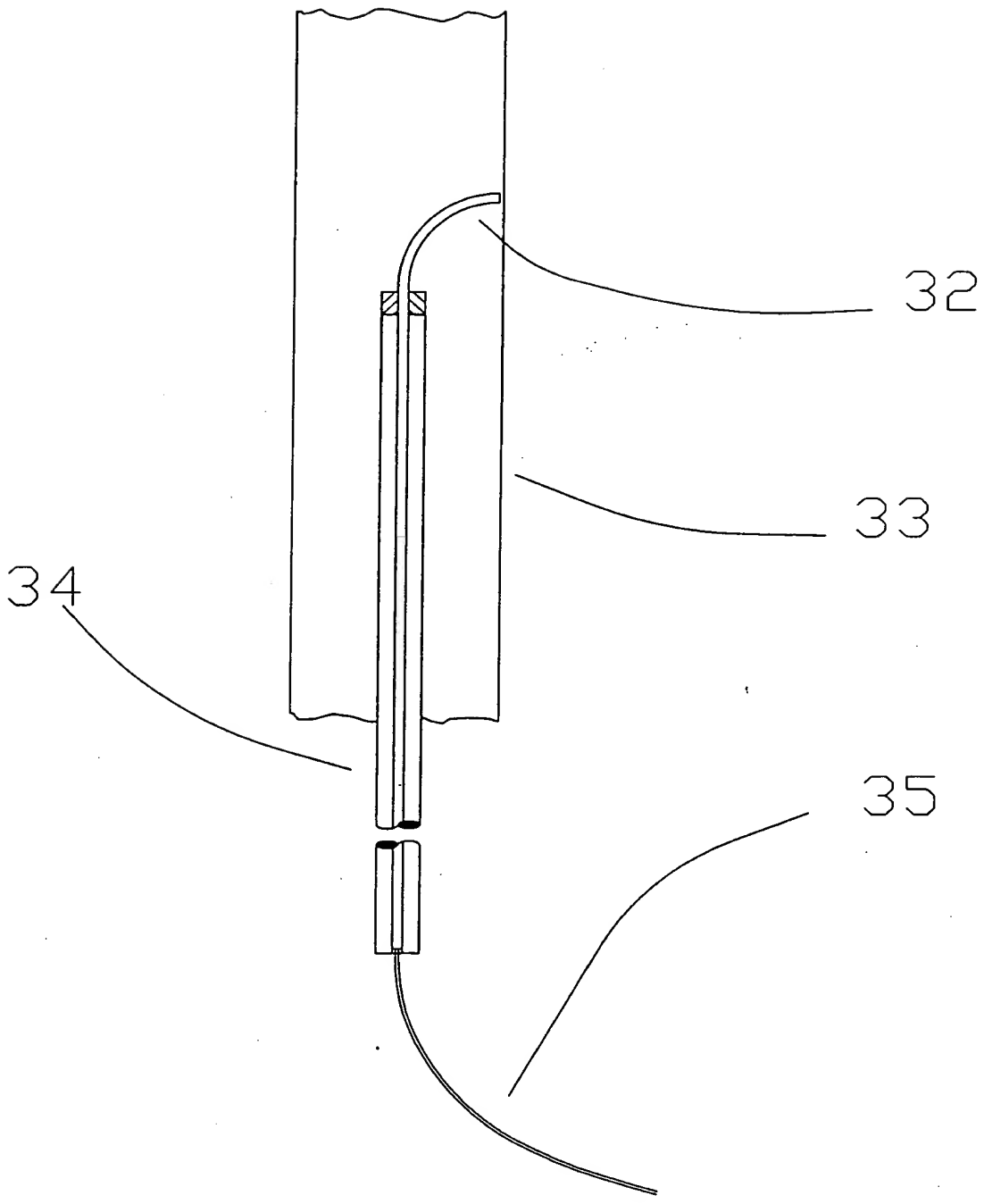


Fig. 9.

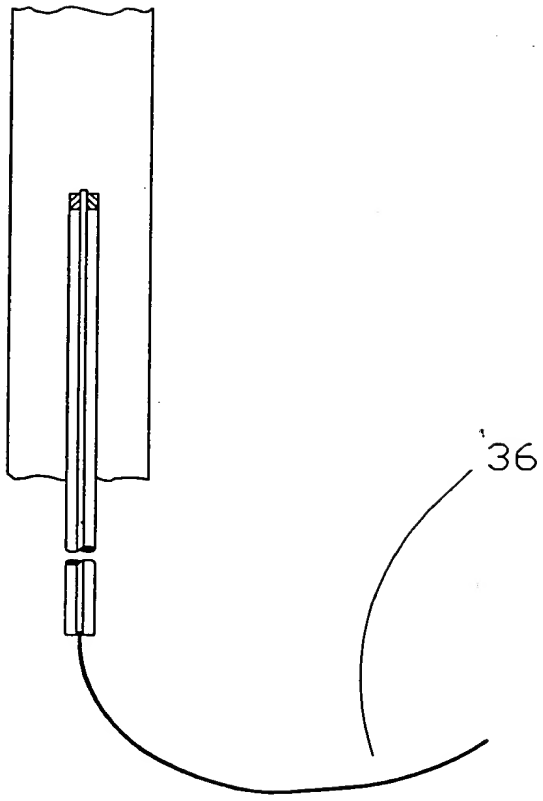
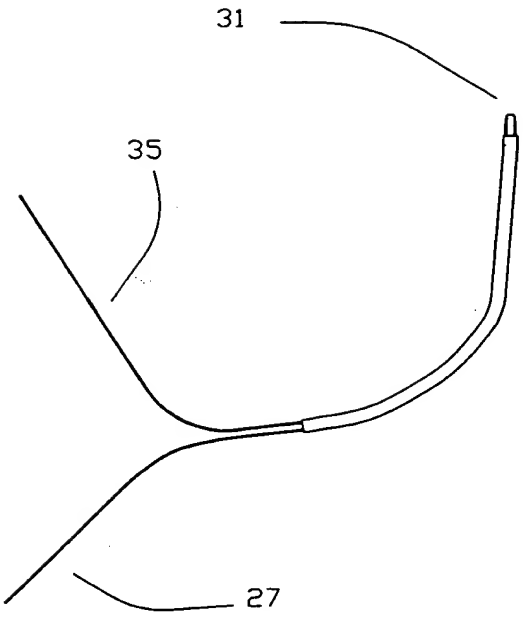
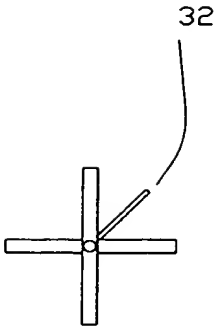
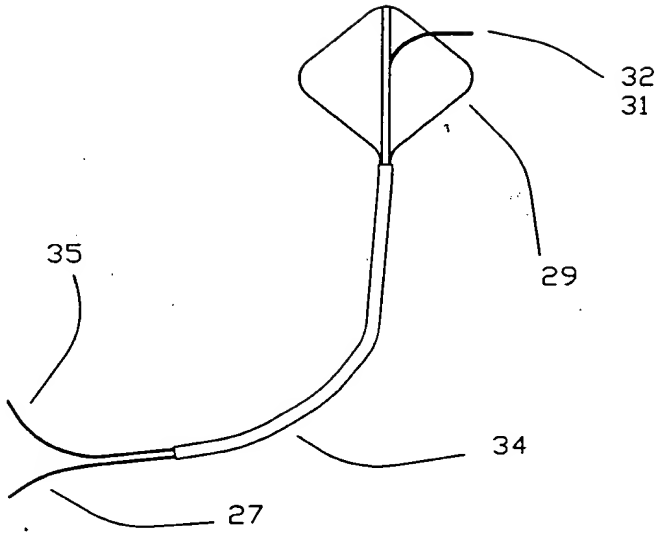


Fig 10







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AGENT : Williams, Powell & Associates